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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BUI, PHUONG T	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 02/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/890,811	Applicant(s) ZHU ET AL.	
	Examiner Phuong T. Bui	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1/18/02* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The Office acknowledges the receipt of Applicant's restriction election filed November 16, 2003. Applicant elects Group I and Invention E (SEQ ID NO:9 encoding SEQ ID NO:10) without traverse. Claims 26-38 are pending and are examined in the instant application. This restriction is made FINAL.

Sequence Listing

2. Applicant's CRF and paper sequence listing have been entered. However, upon examination of SEQ ID NO:9 and its corresponding amino acid sequence SEQ ID NO:10, it is unclear what region of SEQ ID NO:9 encodes SEQ ID NO:10. Clarification is required.

Information Disclosure Statement

3. An initialed and dated copies of Applicant's IDS form 1449, filed January 18, 2002 is attached to the instant Office action.

Claim Rejections - 35 USC § 112, 2nd paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 26-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite percent sequence identity coupled with the functional recitation of "lipid metabolism modifying SNPF1 polypeptide". First of all, "SNPF1" appears to be a misspelling of "SPF1". Accordingly, all recitations of "SNPF1" are interpreted by the

Office to be "SPF1", as supported in the specification. Secondly, while a protein's activity is inherent in the complete protein, the metes and bounds of sequences having less than 100% sequence identity and "lipid metabolism modifying SPF1 polypeptide" activity cannot be assessed because it is unclear what activities are encompassed by such functional recitation. It is also unclear whether there are other SPF1 polypeptides which are not "lipid metabolism modifying"; and whether "modifying" refers to the level of a lipid(s) or the structure(s) of a lipid(s). The specification does not define "lipid metabolism modifying SPF1 polypeptide", or how one skilled in the art would be able to assess which sequences from the 80-95% population are encompassed by the recitation. For example, one skilled in the art can readily determine which sequences have ligase activity, as the name also indicates a particular function. In contrast, while "SPF1" may be an art-recognized protein, one skilled in the art does not know what function is indicated by "SPF1"; and how one would determine which sequences from the 80-95% population would have the asserted activity. Accordingly, without a clearly defined functional recitation, one skilled in the art cannot assess the metes and bounds of sequences having "lipid metabolism modifying SPF1 polypeptide" activity as encompassed by the claims.

The claims recite "Clustal V method of alignment". It is unclear whether the "Clustal V method of alignment" recited in the claims is the same as the "Clustal method of alignment" referred to on page 10 of the specification.

Clarification and/or correction are required.

Claim Rejections - 35 USC § 101 Utility

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 26-38 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility. Applicant asserted that the nucleotide sequence SEQ ID NO:9 encoding SEQ ID NO:10 has "lipid metabolism modifying SPF1 polypeptide" activity.

Applicant states that SEQ ID NO:9 was isolated from soybean and encodes a SPF1 transcription factor homolog (p. 2). Applicant further states that SPF1 may be involved in carbohydrate regulation and storage protein accumulation; may be used in plants to control transcription of particular genes during plant growth, development and response to environmental cues; and "could provide genetic tools to enhance or alter the level of accumulation of seed protein in plants as well as other processes regulated by the SPF1 family of transcription factors" (p. 2). Based upon Applicant's asserted utility for SEQ ID NO:9 and a sequence encoding SEQ ID NO:10, Applicant's asserted utility fails to comply with current utility guidelines for the following reasons. First of all, Applicant's functional assignment for the encoded protein of SEQ ID NO:10 is based solely upon sequence alignment with a single prior art sequence. Applicant provided no empirical data to verify that SEQ ID NO:9 encodes a polypeptide having any SPF1 activity. While empirical data is not required, sequence alignment is generally useful in placing a protein in a particular class but does not replace verification of function. Secondly, assuming *arguendo* that SEQ ID NO:10 has SPF1 activity, it is unclear how

SEQ ID NO:10 can be used to achieve any real-world context of use. Since it is unclear how SPF1 is involved in carbohydrate regulation and storage protein accumulation, one skilled in the art would not be able to use SPF1 to achieve a desirable outcome. How should the SFP1 level in a plant be altered to affect carbohydrate regulation and storage protein accumulation in a useful manner? Furthermore, while having the ability to regulate expression of certain genes at particular stages of plant growth and development is useful, further guidance is necessary as to what gene(s) are regulated, and how such regulation would ultimately result in a useful outcome. What real world use would "control[ling] transcription of particular genes" have if such genes are not disclosed or known in the prior art; and how should the expression level of SEQ ID NO:9 be altered to affect such transcription in a useful manner? It is apparent that further research is required before the claimed polynucleotide would be of benefit to the public. However, the courts have decided that a utility which requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use lacks substantial utility.

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." (Brenner v. Manson, 383 U.S. 519 (1966)).

Thus, while regulating certain genes for certain traits would provide substantial benefit to the public, the claimed invention is not refined and developed to the point where specific benefit exists, as no guidance is provided as to how SEQ ID NO:9 should

be used to alter any specified plant trait. Accordingly, the claimed invention lacks specific asserted utility.

In addressing claims drawn to a sequence having 80-95% sequence identity to SEQ ID NO:9, since SEQ ID NO:9 and a polynucleotide encoding SEQ ID NO:10 lack utility for the reasons set forth above, sequences having less than 100% sequence identity or fragments of these sequences would also lack utility. Applicant should note that no working examples of a sequence having 80-95% sequence identity having "lipid metabolism modifying SPF1 polypeptide" activity are set forth in Applicant's disclosure.

Additionally, there also is no well-established utility for SEQ ID NO:9 and a sequence encoding SEQ ID NO:10. SEQ ID NO:9 does not have a well-established utility for hybridization purposes because the encoded protein does not have utility for the reasons indicated above. Thus, for the reasons set forth, the claimed invention lacks utility under current utility guidelines. (see Utility Examination Guidelines published in Federal Register/ Vol. 66, No. 4/ Friday, January 5, 2001/ Notices; p. 1092-1099).

Claim Rejections - 35 USC § 112, first paragraph

7. Claims 26-38 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Furthermore, the recitation of "lipid metabolism modifying" in the claims is not enabled because "modifying" encompasses increasing, decreasing, as well as altering the structure of the lipid(s) being metabolized. Applicant provided no guidance as to how a single polynucleotide

can function in all three capacities, and in conjunction with what other genes, as lipid metabolism is a complex phenomenon involving multiple pathways and multiple proteins. Claims reciting less than 100% sequence identity are not enabled because they encompass unspecified base deletions, additions, substitutions, and combinations thereof while retaining "lipid metabolism modifying SPF1 polypeptide" activity. While skilled in the art can readily make base changes, further guidance is necessary as to what changes would be tolerated. Further, since it is unclear what such activity would encompass (see 112, 2nd paragraph rejection above), one skilled in the art cannot make and use such sequences without undue experimentation. Accordingly, the claimed invention is not enabled.

Claim Rejections - 35 USC § 112, first paragraph

8. Claims 26-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Applicant is invited to point to the page and line number in the specification where "lipid metabolism modifying SNPF1 polypeptide" can be found. Absent of such support, Applicant is required to cancel the new matter in response to this action.

9. Claims 26-29 and 32-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims reciting 80-95% sequence identity lack adequate written description because Applicant does not disclose a representative number of species as encompassed by these claims. The claims encompass mutants and allelic variants and thus imply that structural variants exist in nature, yet no structural variant has been disclosed. The claims also encompass SPF1 polypeptides from other species. The implication is that there is a gene and a protein other than that disclosed which exists in nature, but the structure thereof is not known. Applicant discloses a single sequence SEQ ID NO:9 isolated from soybean. Thus, there is insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine such mutants, allelic variants and SPF1 polypeptides from other plants and organisms, absent further guidance. Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/ Vol.66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111.

Remarks

10. No claim is allowed. SEQ ID Nos. 9 and 10 are free of the prior art. It is understood by the Office that the Clustal V method of alignment recited in the claims uses the default parameters set forth on page 10, lines 17-19 of the specification. The

closest prior art teaches a sequence isolated from *Ipomoea batatas* having 59.9% sequence identity to SEQ ID NO:10 at the amino acid level.

11. Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Bui whose telephone number is (571) 272-0793.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (571)272-0804.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Phuong Bui
Primary Examiner
Group Art Unit 1638
January 27, 2004

Phuong T. Bui
1/27/04